

allowed. Claims 1-36 presently appear in this application, with claim 1-27 and 30-34 withdrawn from consideration by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claim 29 has been objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 29 is now rewritten in independent form, thereby obviating this objection.

Claim 28 has been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or with which it is most nearly connected, to make and/or use the invention. The examiner indicated that this rejection is based upon the interpretation of the claims wherein the screening step involves the modulation or mediation of a cellular activity.

Claim 28 is now amended to replace the recitation of "cellular activity modulated or mediated by the intracellular domain" with "shedding or proteolytic processing" of the 26 kDa TNF, thereby obviating this rejection.

Claim 28 and 29 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 28 and 29 are held to be indefinite because the examiner indicates that they lack a process step

which clearly relates back to the intended use recited in the claim preamble and it is unclear what process is to be used or achieved in the claimed method. The examiner states that it is unclear whether "screening for a molecule capable of modulating" (claim 28, lines 5-6; claim 29, line 4) entails a "modulating" step as part of the screening process (claims 28 and 29, step "a")), or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. This part of the rejection respectfully traversed.

Applicants submit that "screening" is a process step and this step "screens" for the same molecule recited in the preamble. Therefore, this process step does indeed relate back to the intended use recited in the claim preamble. Applicants further submit that it is not absolutely necessary to specify how the screening is performed as it is only reasonable that this claim covers any type of screen which will identify the appropriate molecule. As a non-limiting example, the present specification on page 15, lines 17-22, teaches a yeast two-hybrid procedure in which the intracellular domains of the 26 kDa TNF are used as "baits" to screen for protein or peptide molecules capable of binding to TNF.

Reconsideration and withdrawal of this part of the rejection are therefore respectfully requested.

2) Claims 28 and 29 are further held to be indefinite over the recitation of "capable of modulating" (claim 28, lines 5-6; claim 29, line 4) because it is unclear

to the examiner whether such "modulating" actually occurs as part of the screening process or whether the molecule is merely capable of such "modulating" and some other type of screening process is intended. The examiner states that an element that is "capable of" performing a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. It is the examiner's position that the metes and bounds of the claim(s) are not clearly set forth. This part of the rejection is respectfully traversed.

The term "capable of modulating" is subject to only one possible interpretation and, thus, is not ambiguous. If the molecule modulates the phosphorylation, shedding or proteolytic processing of the 26 kDa TNF, as presently recited, then it is capable of modulating. The examiner is requested to state how this term could possibly be misconstrued or what other possible meaning it could have. The term "capable of" is not inherently indefinite in the present context. The examiner's attention is invited to MPEP §2173.02, which states that an examiner should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness and that some latitude in the matter of expression and the aptness of terms should be permitted, even though the claim language is not as precise as the examiner might desire. An examiner should not reject claims or insist on his own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

Reconsideration and withdrawal of this part of the rejection are therefore also respectfully requested.

3) The examiner finds the term "directly or indirectly" in claims 28 and 29 to be a relative term which is said to render the claims indefinite. The examiner asserts that the term "directly or indirectly" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree of "directness" or "indirectness", and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. This part of the rejection is respectfully traversed.

Applicants do not understand why recitation of "directly or indirectly" would require a standard for ascertaining the requisite degree of "directness" or "indirectness" in order to be definite. "Directly modulating" is intended to mean that the screened molecule binds to or directly interacts with the 26 kDa TNF to affect the shedding or proteolytic processing of TNF (claim 28) or phosphorylation of the intracellular domain of TNF (claim 29). "Indirectly modulating" means that the modulation of phosphorylation, shedding or processing of TNF occurs not through direct binding or interaction of the molecule with TNF but through its interaction with one or more effector proteins which then interacts indirectly with TNF. See the present specification, paragraph bridging pages 4 and 5.

Reconsideration and withdrawal of this part of the rejection are respectfully requested.

4) Claims 28 and 29 are held to be indefinite by the examiner for reciting a process without any active, positive steps delimiting how this process is actually practiced. This part of the rejection is also addressed above in part 1) of this rejection.

Reconsideration and withdrawal of this part of the rejection are therefore respectfully requested.

The remaining parts of this rejection are obviating by the amendments to the claims.

Claims 28 and 29 have been rejected under 35 U.S.C. 102(b) as being anticipated by Ohta et al. (U). The examiner states that this rejection is based upon an interpretation of the claims, wherein an element that is "capable of performing a function is not a positive limitation but only requires the ability to so perform and therefore, the examiner holds that it does not constitute a limitation in any patentable sense. The examiner asserts that Ohta teaches a process comprising screening for LPS (page 2, full paragraph 4 through paragraph bridging pages 2-3; Figure 1), identifying (page 3, full paragraph 1; Figure 3) and characterizing (page 3, full paragraph 1, through page 4, full paragraph 3) said LPS found by said screening and producing said LPS in substantially isolated and purified form (page 2, full paragraph 3, or Figure 2). This rejection is respectfully traversed.

As discussed above in the U.S.C. §112, second paragraph, rejection, a molecule "capable of modulating" cannot be construed as indefinite and therefore is indeed a positive limitation to be considered in determining

patentability. There is no disclosure in Ohta of screening for a molecule capable of modulating the phosphorylation, shedding or proteolytic processing of the 26 kDa TNF as positively recited in claims 28 and 29. In addition, with regard to new claims 35 and 36, dependent from claims 28 and 29, respectively, Ohta provides no disclosure of testing for binding to the intracellular domain of the 26 kDa TNF as positively recited in claims 35 and 36. Accordingly, claims 28, 29, 35, and 36 cannot be anticipated by Ohta.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By: 

Allen C. Yun
Registration No. 37,971

ACY:pr

624 Ninth Street, N.W.
Suite 300
Washington, D.C. 20001
Facsimile: (202) 737-3528
Telephone: (202) 628-5197